CORRELATIONS BETWEEN CCSVI & MULTIPLE SCLEROSIS
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Multiple sclerosis (MS) affects over 400,000 Americans—each experiencing a unique spectrum of debilitating symptoms. It is with the goal of discourse, education, and hope that V-Aware presents this issue correlating CCSVI with MS.
CONNECTING THE DOTS:
CCSVI AND MULTIPLE SCLEROSIS

The possibility of a connection between chronic cerebrospinal venous insufficiency (CCSVI) and multiple sclerosis (MS) has sparked great interest among patients and healthcare providers alike. And it’s easy to see why—since the first description of MS in 1868 by a professor of neurology at the University of Paris, Jean-Martin Charcot, there remain more questions than answers about the underlying causes and proposed treatments for this disease. MS has long been poorly understood: In the 1940s, it was thought to be related to reduced circulation in the brain; in the 1960s, it was believed to be caused by unknown allergic reactions; and since the 1990s, MS has been described as an autoimmune disease, in which the body’s defense mechanisms (T cells) are inadvertently activated to attack the myelin sheath that surrounds and insulates nerves in the central nervous system.

Over the past 2 decades, much work has been done to try to answer questions regarding the possible viral infectious agents that could start this autoimmune process, the effect of target proteins within the myelin sheaths, and malfunctions in the blood-brain barrier that might allow substances from blood to escape into the brain and initiate the insult that possibly leads to MS. Recently, an Italian vascular surgeon, Paolo Zamboni, has tried to “connect the dots” in this elusive disease and has put forward the concept of CCSVI that might partly contribute to the development and progression of MS. Similar work was reported in 1970 that suggested central venous compression, thrombosis, and hypertension are associated with central nervous system myelopathies; unfortunately, that research went unnoticed.

Now, in 2010, MS affects more than 1 million patients worldwide, usually in the prime of their lives, and the associated healthcare burden is enormous. The difference between today and the MS evolution over the past several decades is that today’s advances in medicine are intimately connected to technological advancements and occur at a pace never witnessed before. Various medical specialists have the ability to exchange information and work productively, and our diagnostic and therapeutic abilities using duplex ultrasound, magnetic resonance angiography, and angiography are much simpler. There is a sense of urgency for patients that are suffering, and preliminary data point toward the validity of CCSVI’s role in MS.

So, where do we go from here? There is no cure for MS, and most therapy today is focused on immunosuppressive agents that blunt the immune system and have significant potential side effects. Preliminary reports on minimally invasive surgery using angioplasty of narrowed central internal jugular and azygous veins, as described by Dr. Zamboni, are encouraging.

All good research leads to more questions than answers, and in this issue of V-Aware, we discuss the contemporary thought processes of neurologists, vascular surgeons, interventionists, researchers, and patients regarding the implications of CCSVI on MS. For physicians and patients to evolve our understanding of the implications of CCSVI, in the near future, prospective and blinded randomized controlled trials will be vital in proving the efficacy of treating CCSVI in MS patients. This truly will be the beginning of a host of technologically advanced therapies that would target CCSVI in ways that we can only imagine today.

I hope you enjoy this issue of V-Aware, and we look forward to your comments and suggestions. Feel free to write to us at info@vaware.org.

Warmest regards,

Manish Mehta, MD, MPH
President and CEO of the Center for Vascular Awareness, Inc., in Albany, NY
Multiple sclerosis (MS) is a disease of the brain and spinal cord, which generally appears in young adults and progresses throughout the rest of the lives of affected patients.

In 85% of patients, the disease follows a relapsing-remitting course; in this form of MS, patients experience attacks wherein they randomly develop neurologic deficits, including loss of vision in one eye, weakness or numbness on one side of the body or in the legs, and poor balance, that may progress over a few days but then lessen over several days or weeks. The symptoms of an attack are quite variable and depend on the part of the nervous system involved. The other 15% of patients with MS present with primary progressive MS in which there are no actual attacks. These people develop a mild neurologic deficit such as weakness or poor balance that gradually progresses over time to become more severe and involve more areas. Many patients with relapsing-remitting MS will develop secondary progressive MS after several years. In this stage, attacks may become fewer, but the disease steadily progresses over time.

MS is quite variable and affects each patient differently. About 20% of patients have what is called benign MS, in which the neurologic problems are minor and not disabling, even after as many as 20 years. Some patients will live their entire adult lives unaware that they have this disease. Others have a much more aggressive course and can be completely disabled early in the course of the disease. Even within the individual, the disease can vary. One patient may have a benign course for 10 or 20 years only to suddenly become disabled by a severe attack.

An individual with fairly active disease may seem to go into remission for several years for no identifiable reason. The unpredictability of the disease course makes research to find treatments for MS all the more challenging.

**SYMPTOMS**

As MS can affect most parts of the brain or spinal cord, the symptoms can be quite variable. Loss of vision in one eye (optic neuritis) is a common complication. Patients may lose function in the arms, legs, or bladder. Dizziness and poor balance are also common. Over time, persistent symptoms develop. Fatigue is very common, as well as pain and muscle spasticity. Later in the disease, memory problems may emerge.

**WHO GETS MS?**

MS is primarily a disease of young adults. Onset is usually between ages 20 and 50, although it may start in childhood. Women are twice as likely as men to develop MS. The disease has an interesting geographic distribution: it becomes more common the further people live from the equator. In North America, for instance, the incidence is greater in the northern parts of the continent. In terms of ethnic and genetic factors, people with Northern European ancestry have a greater risk of developing MS than do people of African or Asian ancestry. A family history of the disease in a first-degree relative also increases risk.
CAUSES
We don’t really know what causes MS. There is a lot we do know, however. The major problem early in the disease is inflammation. MS attacks occur when the immune system attacks myelin, the lining around nerve fibers, in various areas of the brain or spinal cord. This attack causes an MS plaque, which is the diagnostic feature seen on magnetic resonance imaging. The plaque’s location determines the symptoms of the attack. As the inflammation subsides, the symptoms improve. We now know that these plaques leave behind some damage that may build over time. The trigger of the inflammation remains unknown at this time. There may not be one cause for everyone with MS.

DIAGNOSING MS
The most important part of the diagnosis is the patient’s history and physical examination. In order to diagnose MS, a doctor needs to see evidence of a disorder that affects multiple areas of the brain or spinal cord over time. MS cannot be diagnosed based on a single episode until we demonstrate that the problem continues to develop over time. Tests such as magnetic resonance imaging or lumbar puncture may be important tools in the diagnosis of MS but cannot make the diagnosis alone. Patients who suspect they have MS may become frustrated with delays in making the diagnosis, but despite the appearance of MS, the neurologist may have to wait to see how it develops before confirming the diagnosis. Other diseases may look like MS in the early stages, and an accurate diagnosis is critical.

TREATMENT
Because much of the damage is caused by the immune system, the primary treatment of MS involves suppressing or modifying the immune response. For an acute attack, we use high-dose intravenous corticosteroids (also used to treat asthma and other inflammatory diseases). This shortens the duration of the attack and expedites recovery. For long-term treatment, there are several injectable disease-modifying therapies available. These decrease the number of attacks and slow disease progression. Until recently, all of these treatments required regular injections; however, a new oral therapy has just been approved. Several other promising medications designed to alter the immune response are being studied but are not yet approved. In addition to disease-modifying therapies, there are several medications available that treat the symptoms of MS.

If you have been diagnosed with MS, ask your doctor:

1. Should I be taking a disease-modifying agent or medication?
2. What should I do if I notice new symptoms?
3. What are some of the new treatment options for multiple sclerosis?
Investigating Multiple Sclerosis: CCSVI

Multiple sclerosis (MS) has long been viewed as a demyelinating, inflammatory immunological disease. But during the last 165 years, it has also been known to have a perivascular component to it.

Early in the last century, this line of investigation had gained considerable ground with researchers, and neurologists including Tracey Putnam believed that MS was caused by venous obstruction. To test his hypothesis, he studied the effects of obstructed venous flow in the cerebral veins of dogs. These animals developed a number of abnormalities (lesions), many of them similar to encephalitis or MS. Putnam concluded his 1935 article with an observation ahead of its time: “The similarity between [these] lesions and many of those seen in cases of multiple sclerosis in man is so striking, that the conclusion appears almost inevitable that venular obstruction is the essential immediate antecedent to the formation of typical sclerotic plaques.” But Putnam was not the only one who thought that veins played a key role, and in more modern times, a number of people have tried to guide the research community to study the role of the venous system more carefully. In the last few decades, researchers have noted that MS patients have reduced perfusion to the basal ganglia and thalamus.

VENOUS ABNORMALITIES
In September 2009, Dr. Paolo Zamboni openly discussed research that he had been pursuing regarding the role of venous flow abnormalities in MS at a workshop in Bologna, Italy. His data showed that there were major extracranial venous abnormalities in MS patients. He did not claim these abnormalities explained the etiology of MS; rather, he noted that they were associated with MS patients and not generally with healthy subjects. He referred to the resulting condition as chronic cerebrospinal venous insufficiency (CCSVI). In Zamboni’s pioneering work, he showed in an open study of 65 MS patients that there were venous abnormalities such as stenoses, malfunctioning valves, septal flaps, and poor flow in major veins such as the internal jugular veins in the neck and the azygous vein along the spine. Using ultrasound as a screening tool, he described five conditions that helped to assess whether an individual might be classified as having CCSVI. These related to both anatomical conditions (the presence or absence of stenoses) and functional conditions (the presence of abnormal flow, including no flow and reflux flow, often with the accompanying malfunctioning valves or septal flaps).

Zamboni also investigated the role of iron in patients with MS. Iron had been seen in MS lesions long ago, with an article by Adams demonstrating that 30% of patients showed signs of old hemorrhage. Many investigators have also seen increased iron in the basal ganglia and thalamus of MS patients as well. A recent article by Haacke and colleagues suggests that iron builds up backward along the venous system in
the central parts of the brain. This iron may come from red blood cells or a breakdown of brain cells. Free iron can also be damaging to tissue because it is associated with the production of free radicals. In any case, whether or not it is the cause of tissue damage, iron may play the role of a biomarker of tissue damage in patients with MS.

The main thrust of Zamboni’s work is that there are venous abnormalities associated with MS. This finding is not new, and a few other diseases associated with similar venous problems include Budd-Chiari syndrome, idiopathic intracranial hypertension, peripheral vascular disease, global transient ischemia, transient blindness, cough headache, and likely others. Although some of these problems of reduced flow and reflux may be caused by poorly functioning valves, others may relate to the presence of truncular venous malformations and severe narrowing. These venous abnormalities might best be viewed from an embryological background when trying to understand the presence of truncular venous malformations.

**ANGIOPLASTY**

A number of groups around the world are now investigating the safety of angioplasty of the internal jugular veins and the effectiveness of this as treatment for MS. These groups are in the process of preparing their work, and in some cases, manuscripts are in press or in review. Specifically, Ludyga and colleagues report on treatment safety in their first 330 cases. Apart from minor problems with difficulty removing the angioplastic balloon, occlusion of stents, or local bleeding from the groin, they found no major complications (e.g., severe bleeding, venous thrombosis, stent migration, or injury to the nerves). The researchers reported that roughly 60% had bilateral stenoses of a jugular vein, and 40% had unilateral stenoses. Minimally invasive surgical interventions via balloon angioplasty alone was performed in roughly 55% of cases, whereas the stenting of at least one vein was required in roughly 45% of cases. In only 11 cases (3%), no obvious pathology was found despite signs of CCSVI on color Doppler sonography and/or magnetic resonance venography.

**IMAGING**

The venous system is very complicated and varies from person to person. Although truncular venous malformations and diseased valves can be common, in order to properly plan for intervention, I recommend using magnetic resonance imaging (MRI) as a treatment-planning procedure. Having an MRI scan before treatment is crucial for a number of reasons. First, it gives you a baseline picture of the brain tissue; MS lesions; vascular anatomy; flow characteristics; small veins; perfusion, if that is eventually added to the protocol; and iron content; and it reveals any microbleeds or thrombus. Apart from the critical issue of acting as a treatment-planning guide for the interventionalist or vascular surgeon, this information will serve as the baseline from which the practitioner can judge what happens after treatment. For example, do lesions go away, does blood flow improve, does iron content stay the same or reduce? Furthermore, if complications develop, this baseline scan can help determine where the problem lies. Finally, getting an MRI at any time after treatment is a safe procedure that can be done as often as necessary.

**THE VASCULAR ELEMENT**

The work of Zamboni has redirected efforts in MS research into the realm of not just flow and immunology but rather vascular immunology, and this may provide an interesting marriage between cardiovascular and neurodegenerative research. A recent review has promoted this concept as it relates to vascular endothelial health and is written with the focus of MS as a vascular disease. Given the evidence in the literature and the work of many researchers worldwide today, it is hard not to believe that the health and function of the venous vascular system may be strongly associated with MS.

**Ask Your Doctor**

1. Is it possible that Multiple Sclerosis has a venous component to it?
2. Is there any means by which to find out if I have abnormal vasculature in the head, neck or spine?
3. If I have a serious venous obstruction is there anything that can be done about it?
Evidence presented recently in the medical literature proposes that patients with multiple sclerosis (MS) have a coexisting high frequency of obstruction to veins that drain the brain and spinal cord.

These data suggest that MS is associated with blockages in veins located in the neck or chest that alter cerebral venous hemodynamics, causing alterations in venous pressure and flow patterns. This venous obstruction is called chronic cerebrospinal venous insufficiency (CCSVI).

INFLAMMATION
The alterations in venous drainage described above may occur in patients with MS by creating low flow states in the brain and spinal cord that enhance the ability of certain cells within the stagnant or slowly flowing blood to attach to the lining of the vein. Once they adhere to the lining—the so-called blood-brain barrier—immune cells are able to penetrate the wall of the vein and infiltrate the formerly protected brain tissue. After they are across the vein wall, immune cells release a variety of factors to further increase the permeability of the vein wall, enhance migration of various cell types into the surrounding brain tissue, and promote the elaboration of tissue-damaging inflammatory elements.

This active phase of inflammation causes swelling and a high level of stress to the brain tissue that leads to demyelination. Eventually, as the inflammation subsides, the brain tissue resolves with fibrous tissue and plaque formation. In many cases, this situation results in compromised function in the area affected.

A STRONG ASSOCIATION
Dr. Paolo Zamboni and colleagues from Italy have marshaled compelling evidence for CCSVI associated with MS. Using duplex ultrasonography and transcranial Doppler studies, they have documented the frequent association of abnormal venous flow patterns with MS. In one study of 109 MS patients and 177 age- and gender-matched controls, subjects underwent a blinded assessment of five parameters related to cerebral venous outflow using transcranial and extracranial color-Doppler ultrasound examination (TCCS-ECD). In controls, only 2.7% of the measurements were abnormal, whereas in MS patients, 47% of measurements were abnormal. In a study comparing duplex ultrasound with contrast venography, 40% to 70% of patients with MS had evidence of flow disturbances or venous stenosis, or both, by TCCS-ECD. Contrast catheter venography found that 86% and 91% of these patients had obstructions of the azygous or internal jugular veins, respectively.
It is interesting to note that imaging with magnetic resonance shows a prolongation in the time it takes for blood to circulate in and out of the brain—the transit time—in MS patients when compared to patients who do not have MS. This suggests that the obstructions noted by Zamboni and others may have measurable effects on the physiological patterns of blood flow to the brain.

**LOOKING AT CAUSES**

Early observational experience using noninvasive imaging with ultrasound, magnetic resonance, and CT, as well as traditional catheter-based contrast venograms, all indicate that CCSVI includes a spectrum of locations and causes of obstructing venous lesions. The narrowing of a vein may occur at a variety of sites. For example, within the jugular veins in the neck, the obstructions may be high, mid, or low within the vein, and they often are diagnosed at multiple locations.

Similarly, the cause of the venous narrowing may be a range of abnormalities. Some are related to disease affecting the vein itself. These intrinsic vein lesions include thickening of the vein wall due to prior inflammation, scarring following trauma to the vein, and congenital abnormalities affecting a valve typically located within the lower end of the vein as it enters the chest. Alternatively, the vein may be grossly normal but simply narrowed by an extrinsic source, compressed by a structure outside the vein, such as a bone or artery that is anatomically located in a position that contacts the vein. We do not yet understand the relative importance of different sites of venous narrowing or causes of obstruction. It appears that the common thread that laces together all of the CCSVI observations is that venous obstruction exists—the exact location and the exact cause are nonspecific.

**TREATING CCSVI**

It is intriguing to observe that some of the symptoms of MS mimic symptoms observed in patients with superior vena cava syndrome. Obstruction of the superior vena cava, usually caused by a tumor or radiation, impedes venous drainage of the head and neck. Relief of the obstruction with balloon angioplasty and stent placement, if required, provides swift and dramatic resolution of the symptoms of impaired cognition and fatigue. Thus, it is not surprising that patients with CCSVI associated with MS also report rapid relief of these nonlocalizing symptoms after treatment.

The general or global symptoms of fatigue, impaired cognitive performance, and heat intolerance often experienced by MS patients appear to respond to relief of CCSVI obstructions in certain patients. The precise response rate and expected duration of any improvement in symptoms after endovascular treatments are not well established, but numerous trials are actively under development to better define the potential benefits and possible complications of interventional management of CCSVI. Authorities agree that patients who decide to undergo an endovascular procedure should remain on their prescribed disease-modifying drug therapy regimen and not consider interventional therapy a replacement or substitute for established medical treatments.

**Ask Your Doctor**

1. Are you aware of CCSVI and its possible relationship to MS?
2. What are the potential benefits, risks, and complications of endovascular treatment?
3. Would you support my enrollment in a controlled trial to study the effects of endovascular management of CCSVI?
A PATIENT’S STORY: Dhianna

Multiple sclerosis (MS) is a neurological disease that affects more people than you might think—everyday people like your neighbors, friends, or coworkers.

Unfortunately, MS remains poorly understood. If you search the Internet for information on this condition, you will find phrases like “no cure,” “hard to diagnose,” “diagnosis is a challenge,” “you have to rule out in order to rule in,” and other discouraging words.

If medical experts have a difficult time diagnosing MS, how are the rest of us to understand it? Generally, the disease targets the young, usually affecting people in their prime. This was the case with Dhianna, an accomplished 39-year-old business owner who runs a temporary staffing corporation. Unlike a lot of people with MS, she does not suffer from much fatigue and so is still able to log 50- to 60-hour workweeks.

FINALLY DIAGNOSED
Dhianna recalls her first symptoms appearing in September or October of 1993. Tingling on the right side of her body led her to seek the help of a neurologist. A magnetic resonance imaging test of her head was normal. Because she had no other symptoms, no additional testing was ordered. The numbness never went away, however; in fact, she still has that problem today.

In 2006, at age 35, Dhianna developed issues with her gait. She was dragging her left leg, and her coordination and balance were also off. She went to a different neurologist who ordered another magnetic resonance imaging examination of her head, a lumbar puncture (spinal tap), and measurements of her auditory and visual evoked potentials (nervous system responses). This time, the test results came back positive, and the diagnosis of MS was made.

When she was told that she had MS, Dhianna recalls experiencing a feeling of relief because her symptoms finally had an explanation—and because she had always suspected that MS was the cause.

Her symptoms have changed how Dhianna spends her time. In high school, she was active in sports. She played basketball and softball and participated in an indoor soccer league until 5 years ago. When asked how MS affects her day-to-day life, Dhianna replied, “Because my coordination is off, it takes longer to accomplish tasks.” She says she also doesn’t ski or snowboard anymore due to her balance issues. She does work out with a personal trainer, focusing on strengthening her core in order to help improve her balance.
**LIVING WITH MS**
Dhianna struggles with MS on a daily basis. “I have the ‘relapsing-and-remitting’ form of MS. My husband lost a close friend to MS not too long ago,” she says. “So it’s something we think about. But we don’t really discuss my disease.”

MS is often an “invisible” disease, because people who suffer from it frequently try to live normal lives as much as possible: For example, Dhianna has a brace for her left leg but doesn’t wear it because, she says, “it doesn’t look good.” Dhianna manages to maintain a hopeful outlook, however. Her twin brother is healthy, and she credits her parents with also being a positive force in her life.

**WORTH THE RISK**
Dhianna takes a number of expensive medications to help slow down the progression of her disease. Seeking an option that might be more curative, Dhianna decided to enter into a clinical research trial called *Utility of Chronic Cerebral Spinal Venous Insufficiency Percutaneous Angioplasty for Multiple Sclerosis: The Albany Vascular Group Study* (which involves a venogram and a 2 to 1 chance of randomization to the angioplasty procedure vs the sham procedure (venogram only). The goal of the treatment is to evaluate the trye benefits of opening up narrowed central veins in Multiple Sclerosis patients.

“I looked into the procedure. I do not feel there are many risks, not like injecting yourself every day with a drug,” Dhianna said. “Sometimes you have to take a risk. If this is a physical disease, not an autoimmune issue, this procedure could have a positive effect. Why wouldn’t I want to be a part of it?!” After the procedure, Dhianna will continue to take her prescribed medications.

Dhianna enrolled in the study and was treated by Dr. Manish Mehta a vascular surgeon of The Vascular Group in Albany, NY. The day after the procedure Dhianna said, “I feel like a superstar. I have definitely felt improvement. My husband has noticed a big change.” Describing the experience, Dhianna said, “Undergoing the venogram was easy. I don’t really remember much of anything. It was very quick and painless.” When asked what improvements she felt, she said that she was able to walk better and that she could stand up from a sitting position on the floor. She also felt she was moving smoother and added, “I do feel that my head is clearer.”

Within a week Dhianna felt that she had 20-25% improvement over her preprocedure baseline. “I don’t drag my leg as much, and I’m able to lift my feet when I walk. The numbness in my right side is not so tingly. My husband says that I get up from the couch much more easily, and I don’t feel like I am going to tumble over.”

Because of the nature of this research trial, Dhianna does not know if she received treatment or a placebo procedure. Due to her significant improvement, however, both Dhianna and her husband believe she was treated.

Before undergoing the procedure, Dhianna had looked at the pros and cons of just allowing her MS to progress naturally versus participating in the study. “Why would I let that happen? I am very pleased and incredibly happy that I enrolled in the study with The Vascular Group in Albany.”

-by Sharon Cillis

For more information about research trials, go to:

[www.clinicaltrials.gov](http://www.clinicaltrials.gov)
THE VALUE of Randomized Controlled Trials

There is a great amount of work to be done in solving the multiple sclerosis (MS) riddle. Clinical research trials study new drugs, devices, and treatment options to provide the evidence needed for physicians to determine how to deliver the best possible care to their patients.

Published medical literature from well-structured research trials provides the fundamental evidence that helps healthcare providers to make informed conscientious decisions and choose the best possible therapy for their patients.

HOW CARE EVOLVES
The fundamentals of evolving medical care begin with research, and what is considered research today can readily evolve into the standard of care tomorrow. There are thousands of examples of this in medicine; for example, look at the evolving treatments of patients with heart disease. The frustration of being unable to prevent heart attacks led researchers to discover cholesterol’s major role in plaque formation and hardening of the arteries resulting in heart attacks. In the 1970s, research trials provided the first scientific data supporting the ability of drugs called statins (or HMG-CoA reductase inhibitors) to lower elevated cholesterol levels. During the same time, physicians were finding better ways of treating patients with significant coronary artery disease that resulted in heart attacks. The only available options at that point were minimally invasive coronary artery angioplasty or open heart surgery, which carried a significant risk. We have long understood that angioplasty alone, whether it is in arteries or veins, does not result in long-term successful outcomes, and adjunctive devices such as stents are often required. Of course, it is through vigorous research and randomized controlled trials that the appropriate stents that would conform well to the coronary arteries were developed. All along, drugs such as aspirin and Plavix that further help prevent clotting were refined to help increase the longevity of the stents.

In just 3 decades, through well-structured research, we have made great strides in managing patients with heart disease. It is not surprising that it took at least three different disciplines of medicine to “connect the dots” in improving treatment options. Today, the early diagnosis of cardiac risk factors, combined with treatment using drugs such as statins to lower patients’ cholesterol levels, helps prolong lives. Improvements in stent design and procedures including heart bypass have has led us to finding the appropriate treatment paths for individual patients that only a few decades ago would have had limited options.
RANDOMIZATION IS KEY
In MS, patient symptoms are often subjective—that is, we have not figured out a way to measure them objectively—and it is this aspect of the disease that mandates a randomized, double-blinded, placebo-controlled trial to evaluate new treatment options. When evaluating the connections between chronic cerebrospinal venous insufficiency (CCSVI) and MS, one has to study the impact of dilating confirmed blockages in the central veins by venoplasty. The randomization has to be between a venoplasty and a sham procedure, where the patients are blinded to the procedure and do not know which treatment they received. The physicians evaluating patients’ outcomes are blinded to the procedure as well (this is called double blinding). Study subjects volunteer to participate knowing they will randomly be assigned to receive the treatment or a placebo. Randomizing eliminates any bias that could occur by the researchers conducting the trial, and the use of probability theory ensures that any differences or similarities in outcome between the treatment groups are not merely by chance. Data is collected from both the treatment and the sham groups of patients, and the results are analyzed.

THE VALUE OF RESEARCH
Just as research from over the past several decades has provided the building blocks that have led to Dr. Paolo Zamboni’s work connecting the dots between CCSVI and MS, today’s research will provide information that will enable doctors and healthcare providers to make better decisions and further improve on currently available therapy.

There is a social value of clinical research, especially when the trial results establish that a particular method of treatment is effective and safe for treating, curing, or preventing an illness. The value of research is found in its ability to collect information that might be useful to identify improved methods to treat medical illnesses.

To find the answers for new and better ways to treat disease, sometimes it takes one scientist, one doctor, and one patient to start the journey of scientific discovery. Thankfully, there are patients volunteering to participate in randomized trials knowing they may not receive treatment, doctors willing to devote their time and attention to create scientific protocols, and investigational review boards willing to approve safe studies that can evaluate a treatment option outside the mainstream view of the time.

THE NEED FOR FUNDING
Hopefully, this valuable research will continue to be funded. Philanthropic efforts from charitable individuals, patients, medical societies, industry, and the National Institutes for Health are necessary to fuel the financial support needed to run clinical trials. Today more than ever, grass-roots efforts are also needed to initiate these large-scale projects. Public awareness campaigns that support research will help encourage even more community members to become involved.

For more information about ongoing CCSVI and MS research, go to:
www.vaware.org, or
www.clinicaltrials.gov
Life Goes On: FACING MULTIPLE SCLEROSIS

Christine Sisto Mertes had just celebrated her 30th birthday, and life was good. She had a great husband and a fabulous job, but then her world crashed.

She awoke one morning and had lost her cognitive functions. She couldn't read or write, or remember how to log on to her computer. As Christine describes it, “Everything I'd learned from kindergarten through grade 12 was gone.”

When Kimberly Adams Russell was 35 years old, she had three children, twin 1 year-old girls and a 6 year-old son. Besides running her household, she was also running a business, and the building was undergoing renovation—a construction job fraught with problems. Kimberly was stretched to the limit. But she never expected to wake up one morning to find the entire left side of her body numb. Her husband carried her into the shower, but when the unsettling numbness persisted, he helped her dress, carried her to the car, and drove to her primary care doctor.

A NEW VIEW
Both women feared the worst in the face of these sudden breakdowns: brain tumor, cancer—something untreatable and deadly. Both were wrong. In short order, the same day for Kimberly and by week's end for Christine, they were diagnosed with the relapsing-remitting form of multiple sclerosis (MS). When Christine heard those words, she says she crumpled to the ground, almost unable to breathe. She was devastated, imagining a future in a wheelchair.

That fear provided her first lesson about MS: The image of a lifetime bound to a wheelchair is an old view of the disease. As her doctor explained, treatment advances over the past 10 years meant she had a very good chance of remaining active for most, if not all, of her life.

STAYING “ALIVE”
And she has. Since her diagnosis, Christine, who began studying dance when she was 4, continues teaching ballet to children. She is part owner of Capital Affairs, an event planning and promotions company that keeps her on her toes, often into the weekend. She also did something she figured she would never do, MS or not: become a mother. Christine says the diagnosis of MS forced her to take a hard look at her life and reorient her priorities. The support of her family, she says, got her through her “darkest days,” warming and opening her heart to having a family of her own. She and her husband are now the proud parents of two children.

As for Kimberly, she, too, thought the worst when she awoke that morning, numb on one side. With her quick diagnosis came relief, as she puts it, that her problem “was just MS.” Kimberly is a strong spirit in a petite package, and knowing hers was a treatable disease, she knew she had options and could take action. Within 5 days of that
Both women spread their own message of hope as they mentor others who are diagnosed with MS, in an effort to encourage them to seek treatment and be proactive in their care. When I asked them what they’d like to see come down the treatment highway, they responded, “More oral medications.” The injectable medications are difficult to endure year after year, so they understand why some patients may choose to forego that approach. It’s tough enough living with a chronic illness, they’ll tell you, but the skin breakdown from the injections, for some, is one insult too many.

If these women could speak directly with MS researchers, they’d ask them to ramp up work on treatment for those with the progressive form of the disease. It upsets them that others continue to struggle with progressive MS, while breakthroughs in treatment for their form of the disease, relapsing-remitting MS, are more forthcoming.

And for those of us who haven’t been touched by this disease, Christine and Kimberly call for a little more education about MS, because the stigma of MS persists. As these dynamic women tell you, they don’t need your pity; they need your understanding, strength, and commitment to finding a cure for what ails them.
What is CCSVI? Chronic Cerebrospinal Venous Insufficiency is a result of venous blood flow abnormalities in the central neck and chest veins that might impair cerebral venous blood flow in Multiple Sclerosis patients.

How do I know if I have CCSVI? A duplex ultrasound will be able to test the blood flow in your neck. A venogram will confirm the results of the duplex ultrasound. Both tests will be used in conjunction to confirm a diagnosis of CCSVI.

Will treating CCSVI cure my MS? We don’t know. That is why we are doing a research study. If you answered yes to all of the questions below, contact Megan Wilcox, Research Coordinator, Center for Vascular Awareness, Inc., at 518-218-7909.

ARE YOU BETWEEN THE AGES OF 18 AND 55?
HAVE YOU BEEN DIAGNOSED WITH RELAPSING REMITTING OR SECONDARY PROGRESSIVE MS?
ARE YOU WILLING TO PARTICIPATE IN A RESEARCH TRIAL THAT MAY HELP SHOW THE CORRELATION BETWEEN MS AND CCSVI?

Center for Vascular Awareness, Inc. & The Vascular Group, PLLC, are currently enrolling MS patients in a Single Center, Multispecialty, Randomized Double Blind Placebo Control Feasibility Clinical Trial:

“UTILITY OF CHRONIC CEREBROSPINAL VENOUS INSUFFICIENCY PERCUTANEOUS ANGIOPLASTY FOR MULTIPLE SCLEROSIS: THE ALBANY VASCULAR GROUP STUDY”

The Principal Investigator is Manish Mehta, MD, MPH, and this study will be conducted at The Vascular Health Pavilion
5 Pine West Plaza, Suite 501
Albany, New York 12205
The Vascular Group was founded to establish a comprehensive vascular care center consisting of board-certified vascular specialists trained in endovascular, angiographic, and surgical techniques. Our physicians distinctively combine expertise in both traditional open surgery and cutting-edge, minimally invasive catheterization techniques to manage peripheral vascular disease. We are committed to promoting vascular health and delivering the highest-quality care to our patients and our community.

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Chronic cerebrospinal venous insufficiency (CCSVI) is a result of venous blood flow abnormalities in the central neck and chest veins that might impair cerebral venous blood flow in multiple sclerosis patients.

The Vascular Group in Albany and the Center for Vascular Awareness (a not-for-profit organization) are conducting research trials to better understand the implications of CCSVI in multiple sclerosis patients.

www.clinicaltrials.gov